7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8. CORRECTED DRAWINGS must be submitted.  (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1) hereto or 2) to Paper No.  (b) including changes required by the proposed drawing correction filed , which has been approved by to including changes required by the attached Examiner's Amendment / Comment or in the Office action of Pathentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsp.  3. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  1. Notice of References Cited (PTO-892)  2. Notice of Informal Patent Application Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Notice of Draftperson's Patent Drawing Review (PTO-948)  3. Information Disclosure Statements (PTO-1449), Paper No.  3. Family Review (PTO-9413), Paper No.		
Jeanine A Goldberg   Jeanine A Goldberg   Jeanine A Goldberg	۸L.	
The MAILING DATE of this communication appears on the cover sheet with the correspondence herewith (previously mailed), a Notice of Allowance (PCTOL-85) or other appropriate communication is enjoication. If not it herewith (previously mailed), a Notice of Allowance (PCTOL-85) or other appropriate communication is made of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.  1. □ This communication is responsive to 25/03.  2. □ The drawings field on are accepted by the Examiner.  4. □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) □ All   b) □ Some* (c) □ None of the:  1. □ Certified copies of the priority documents have been received.  2. □ Certified copies of the priority documents have been received in Application No  3. □ Copies of the certified copies of the priority documents have been received in this national stage application and the priority documents have been received in this national stage application of the certified copies of the priority documents have been received in this national stage application of the certified copies of the priority documents have been received in this national stage application of the foreign language provisional application has been received.  5. ☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  (a) □ The translation of the foreign language provisional application has been received.  5. ☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 120 and/or 121.  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS 1.  7. □ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8. □ CORRECTED DRAWINGS must b		
hereawth (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication is benefited in NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal fron of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.  1.		
2. ☑ The allowed claim(s) is/are 1-46. 3. ☐ The drawings filed on	cluded	
2. Me allowed claim(s) is/are 1.46. 3. The drawings filed on		
4.		
a)		
2.		
3.		
International Bureau (PCT Rule 17.2(a)).  * Certified copies not received:  5. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  (a) The translation of the foreign language provisional application has been received.  6 Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS 1  7 A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8 CORRECTED DRAWINGS must be submitted.  (a) including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached		
* Certified copies not received:	olication fr	rom the
(a) ☐ The translation of the foreign language provisional application has been received. 6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS 17. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8. ☐ CORRECTED DRAWINGS must be submitted. (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) ☐ hereto or 2) ☐ to Paper No  (b) ☐ including changes required by the proposed drawing correction filed, which has been approved by the including changes required by the attached Examiner's Amendment / Comment or in the Office action of Patentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Drafts;  9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  3. ☐ Information Disclosure Statements (PTO-1449), Paper No  4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material		
Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS 1.  7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8. CORRECTED DRAWINGS must be submitted.  (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No  (b) including changes required by the proposed drawing correction filed, which has been approved by the including changes required by the attached Examiner's Amendment / Comment or in the Office action of Pall Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Drafts; and DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted extrached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  **Attachment(s)**    Notice of References Cited (PTO-892)		
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS 1 7.   A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  CORRECTED DRAWINGS must be submitted.  (a)   including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1)   hereto or 2)   to Paper No  (b)   including changes required by the proposed drawing correction filed, which has been approved by the including changes required by the attached Examiner's Amendment / Comment or in the Office action of Palldentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsp.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  Notice of References Cited (PTO-892)  Notice of Draftperson's Patent Drawing Review (PTO-948)  Information Disclosure Statements (PTO-1449), Paper No  Examiner's Comment Regarding Requirement for Deposit of Biological Material		
7. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8. CORRECTED DRAWINGS must be submitted.  (a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No  (b) including changes required by the proposed drawing correction filed, which has been approved by the comment of including changes required by the attached Examiner's Amendment / Comment or in the Office action of Palledntifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top many of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsp.  9. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  10. Notice of References Cited (PTO-892)  11. Notice of Draftperson's Patent Drawing Review (PTO-948)  12. Notice of Informal Patent Application interview Summary (PTO-413), Paper No  13. Information Disclosure Statements (PTO-1449), Paper No  14. Examiner's Comment Regarding Requirement for Deposit of Biological Material		
7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.  8. ☐ CORRECTED DRAWINGS must be submitted.  (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1) ☐ hereto or 2) ☐ to Paper No  (b) ☐ including changes required by the proposed drawing correction filed, which has been approved by the comment of including changes required by the attached Examiner's Amendment / Comment or in the Office action of Patentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftspart.  9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  3. ☐ Notice of Praftperson's Patent Drawing Review (PTO-948)  4. ☐ Information Disclosure Statements (PTO-1449), Paper No  5. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material  9. ☐ Other	equireme	ents noted
(a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  1) hereto or 2) to Paper No  (b) including changes required by the proposed drawing correction filed, which has been approved by to including changes required by the attached Examiner's Amendment / Comment or in the Office action of Pall Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marge of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson's Pand/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  Notice of References Cited (PTO-892)  Notice of Draftperson's Patent Drawing Review (PTO-948)  Information Disclosure Statements (PTO-1449), Paper No  Examiner's Comment Regarding Requirement for Deposit of Biological Material  Other		
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached  1) ☐ hereto or 2) ☐ to Paper No  (b) ☐ including changes required by the proposed drawing correction filed, which has been approved by the including changes required by the attached Examiner's Amendment / Comment or in the Office action of Patentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marge of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson's Patent Drawing Requirement for Deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  ☐ Notice of References Cited (PTO-892) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) ☐ Information Disclosure Statements (PTO-1449), Paper No ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material  2 Notice of Informal Patent Application Interview Summary (PTO-413), Patentify Statement of Reasons of Biological Material		
1)  hereto or 2)  to Paper No  (b)  including changes required by the proposed drawing correction filed, which has been approved by the comment of including changes required by the attached Examiner's Amendment / Comment or in the Office action of Palledentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marge of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Drafts; attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  Notice of References Cited (PTO-892)  Notice of Draftperson's Patent Drawing Review (PTO-948)  Information Disclosure Statements (PTO-1449), Paper No  Examiner's Comment Regarding Requirement for Deposit of Biological Material  Other  Other		
Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Pall Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Drafts; and the official		
Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Pall Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top marg of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Drafts; and the official	ne Examir	ner.
DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  Notice of References Cited (PTO-892)  Notice of Draftperson's Patent Drawing Review (PTO-948)  Information Disclosure Statements (PTO-1449), Paper No  Examiner's Comment Regarding Requirement for Deposit of Biological Material  Notice of Biological Material	er No	
DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.  Attachment(s)  Notice of References Cited (PTO-892)  Notice of Draftperson's Patent Drawing Review (PTO-948)  Information Disclosure Statements (PTO-1449), Paper No  Examiner's Comment Regarding Requirement for Deposit of Biological Material  2 Notice of Informal Patent Application deposit of Examiner's Amendment/Comment sequence of Examiner's Statement of Reasons of Biological Material	n (not the	back)
<ul> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statements (PTO-1449), Paper No</li> <li>Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> <li>2 Notice of Informal Patent Application</li> <li>Interview Summary (PTO-413), Paper No</li> <li>Examiner's Amendment/Comment</li> <li>8 Examiner's Statement of Reasons</li> <li>Other .</li> </ul>		ne
B Notice of Draftperson's Patent Drawing Review (PTO-948)  □ Information Disclosure Statements (PTO-1449), Paper No  □ Examiner's Comment Regarding Requirement for Deposit of Biological Material  □ Other  □ Other		
Notice of Draftperson's Patent Drawing Review (PTO-948)   4	n (DTO 1	(50)
☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material  6☐ Examiner's Amendment/Comment 8⊠ Examiner's Statement of Reasons 9☐ Other .	n (P10-1) per No.	.02)
of Biological Material 9 ☐ Other .		
	or Allowa	ince
JEFFREY		
	FREDMA	AN
PRIMARY		

Art Unit: 1634

## **DETAILED ACTION**

- 1. This action is in response to the after final amendment filed February 5, 2003.
- 2. Claims 1-46 are pending.

## **REASONS FOR ALLOWANCE**

3. The following is an examiner's statement of reasons for allowance.

In view of the declaration filed February 5, 2003 and the terminal disclaimer filed disclaiming 09/493,353, Claims 1-46 are allowable.

The claims are drawn to methods which require using one or more pairs of oligonucleotide primers specific for the 5' noncoding region of HCV and one or more pairs of oligonucleotide primers specific for HIV produce amplification products. The claims require that the HCV primers are SEQ ID NO: 1 and 2, namely the primers C131F25 and C294R25. Moreover, each of the products and kit claims require the primer pair of SEQ ID NO: 1 and 2.

As provided in application 09/493,353, the primers of C131F25 and C294R25 are found to have unexpected results. The specification of 09/493,353, on pages 24, 26 illustrate that the primers C131F25 and C294R25 do not detect any false positives like the Roche primers. Therefore, the obviousness of the primers has been overcome by the demonstration of unexpected results.

Moreover, the double patenting rejection has been overcome in view of the terminal disclaimer.

Application/Control Number: 09/494,332

Art Unit: 1634

- Page 3
- 4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg March 18, 2003

> JEFFREY FREDMAN PRIMARY EXAMINER